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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,026	10/06/2000	Anthony Louis Devico	11076-002001	3193

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EXAMINER	
WINKLER, ULRIKE	
ART UNIT	**PAPER NUMBER**
1648	9

DATE MAILED: 02/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Applicati n N .	Applicant(s)	
	09/684,026	DEVICO ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler, Ph.D.	1648	

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) 1-72 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-72 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-17 and 24, drawn to a chimeric polypeptide wherein the polypeptide is selected from *Retroviridae* (HIV, SIV, FIV, FeLV), classified in class 424, subclass 207.1.

2. Claims 1-5, 10-17 and 24, drawn to a chimeric polypeptide wherein the polypeptide is selected from *Parvoviridae* (FPV = feline panleukemia virus), classified in class 424, subclass 233.1.

3. Claims 1-5, 10-17 and 24, drawn to a chimeric polypeptide wherein the polypeptide is selected from *Herpesviridae*, classified in class 424, subclass 229.1.

4. Claims 18-23, drawn to a chimeric polypeptide which contain a third heterologous domain, classified in class 424, subclass 193.1.

5. Claims 25-28, drawn to a polynucleotide encoding a chimeric polypeptide, classified in class 536, subclass 23.4.

6. Claims 29-33, drawn to an antibody to the chimeric polypeptide, classified in class 530, subclass 388.3.

7. Claims 34-43 and 45, drawn to a method of administering an effective amount of chimeric polypeptide to achieve antibody production, classified in class 800, subclass 3.

8. Claims 34-43 and 45, drawn to a method of administering an effective amount of a polynucleotide encoding the chimeric polypeptide to achieve antibody production, classified in class 800, subclass 3.

9. Claims 38 and 44, drawn to a method of administering an effective amount of chimeric polypeptide to achieve a CTL response, classified in class 800, subclass 3

10. Claims 38 and 44, drawn to a method of administering an effective amount of a polynucleotide encoding the chimeric polypeptide to achieve a CTL response, classified in class 800, subclass 3.

11. Claims 46-65, drawn to a method of identifying an agent that inhibits an interaction between the virus and a co-receptor or virus and a receptor, classified in class 436, subclass 501.

12. Claims 66-72, drawn to a method of identifying an agent that inhibits viral infection of a cell, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Groups 1-6 are compositions and are distinct from groups 7-12 which are drawn to methods. Groups 1-6 are compositions and each is distinct from the other because they contain different materials. Group 1 comprises a chimeric polypeptide containing *Retroviridae* sequences. Group 2 comprises a chimeric polypeptide containing *Parvovirdae* sequences. Group 3 comprises a chimeric polypeptide containing *Herpesviridae* sequences. Group 4 comprises a chimeric polypeptide containing three protein sequences including an

immunomodulatory sequence. Group 5 comprises the polynucleotide sequence for the chimeric protein; and DNA is made up of nucleic acids. Group 6 comprises an antibody to the chimeric protein, although antibodies themselves are proteins, they are different molecules with different structures. Though there may be overlap for these groups, the search for one group will not be coextensive with that of the other group.

Groups 7-12 are drawn to methods and each is distinct from the other because they utilize different starting materials, therefore the outcomes are not expected to be the same. Groups 7 and 9 are drawn to a method for administering an effective amount of chimeric polypeptide. Group 7 the administration of the chimeric protein results in an antibody production response while the result with group 9 is to produce a CTL response. Groups 8 and 10 are drawn to administering a polynucleotide. Group 8 the administration of the chimeric protein results in an antibody production response while the result with group 10 is to produce a CTL response. Group 11 is drawn to a method of identifying an agent that inhibits the binding of the virus to the receptor or co-receptor. Group 12 is drawn to a method of identifying an agent that inhibits viral replication in a cell. The method of groups 11 and 12 uses different steps from the other methods, thereby setting them apart. Groups 7-10 differ from each other by utilizing different starting materials and techniques, the outcome would therefore not be expected to be the same.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

Claim 1 link(s) inventions 1-3. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Group 1 contains the following species of immunodeficiency virus:

1) HIV
2) SIV
3) FIV
4) FeLV

The above listed species are distinct because they encode different viral polypeptides and the infection of one species of virus will not provide protection from infection by another species of virus, indicating that the polypeptides are unique to each species. The examination of species

1-4 in the composition would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability.

Group 11 contains the following species of test agents:

a) peptide
b) organic molecule
c) antibody
d) antiviral
e) immunodeficiency virus co-receptor

The species differ in their physical and structural properties and are distinct and unobvious in view of each other and are therefore patentably distinct. The examination of species a-e in the method parameters would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1, 46 and 57 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.

JEFFREY STUCKER
PRIMARY EXAMINER